K071317

AUG 2 0 2007

510(k) Submission Information:
Device Manufacturer: Dade Behring Inc.
Contact name: Robert Eusebio, Regulatory Affairs Manager
Fax: 916-374-3144
Date prepared: May3, 2007
Product Name: Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name: MicroScan® Synergies plus™ Gram-Positive MIC/Combo Panels
Intended Use: To determine antimicrobial agent susceptibility
510(k) Notification: New antimicrobial - Gentamicin Synergy Screen
Predicate device: MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panels and MicroScan® Dried Gram-Positive Panels

510(k) Summary:

MicroScan® Synergies plus™ Gram-Positive MIC/Combo Panels, utilizing both the MicroScan® Rapid Fluorogenic Identification and Dried Overnight Antimicrobial Susceptibility Testing (AST) technologies, are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-positive enterococci and staphylococci.

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in water and dehydrated. Various antimicrobial agents are diluted in water, buffer, or minute concentrations of broth, to concentrations bridging the range of clinical interest. Panels are rehydrated with Synergies plus™ Pos Broth, after inoculation with a standardized suspension of the organism. After incubation in the WalkAway® *SI,* or equivalent, System, for 4.5 - 18 hours, the minimum inhibitory concentration (MIC) for the test organism is read by determining the lowest antimicrobial concentration showing inhibition of growth.

The proposed MicroScan® Synergies plus™ Gram-Positive MIC/Combo Panel demonstrated substantially equivalent performance when compared with a frozen Reference Panel, as defined in the FDA document "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA", dated February 5, 2003. The Premarket Notification (510[k]) presents data in support of the MicroScan® Synergies plus™ Gram-Positive MIC/Combo Panel with Gentamicin Synergy Screen.

The external validation was conducted with fresh and stock Efficacy isolates and stock Challenge strains. The external validations were designed to confirm the acceptability of the proposed Synergies plus™ Gram-Positive Panel by comparing its performance with a frozen Reference panel. Challenge strains were compared to Expected Results determined prior to the evaluation. The Synergies plus™ Gram-Positive Panel demonstrated acceptable performance with an overall Categorical

Agreement of 97.0% for Gentamicin Synergy Screen when compared with the frozen Reference panel.

Instrument reproducibility testing demonstrated acceptable reproducibility and precision for Gentamicin Synergy Screen with Turbidity inoculum preparation method and the WalkAway® *SI* System or equivalent.

Quality Control testing demonstrated acceptable results for Gentamicin Synergy Screen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Robert Eusebio
Regulatory Affairs Specialist
Dade Behring, Inc.
2040 Enterprise Blvd
West Sacramento, CA 95691

AUG 2 0 2007

Re: K071317
Trade/Device Name: MicroScan® Synergies plus™ Gram-Positive MIC/Combo Panels with Gentamicin Synergy Screen (500µg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices
Regulatory Class: Class II
Product Code: LON, LRG, JWY, LLT
Dated: May 9, 2007
Received: August 7, 2007

Dear Mr. Eusebio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071317

Device Name: MicroScan® Synergies plus™ Gram-Positive MIC/Combo Panels with Gentamicin Synergy Screen (500 µg/ml)

Indications For Use:

The MicroScan® Synergies plus™ Gram-Positive MIC/Combo Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-positive enterococci and staphylococci. After inoculation, panels are incubated for 4.5 – 18 hours at 35°C +/- 1°C, in a WalkAway® *SI*, or equivalent, and read by the MicroScan® Instrumentation. Additionally, the panels may be incubated in a non-CO_2 incubator and the Antimicrobial Susceptibility Testing (AST) portions can be read visually, according to the Package Insert.

This particular submission is for the addition of the antimicrobial Gentamicin Synergy Screen, at a concentration of 500 µg/ml, for enterococci, to the test panel.

The gram-positive organisms which may be used for Gentamicin Synergy Screen susceptibility testing in this panel are:

Enterococcus species

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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